

INTRODUCTION



Our conference theme for CEAC 2019 – 'New Horizons' points to the future – but captures the idea that not all future gazing is about how current issues and ideas will evolve. Thinking about the coming challenges for our industry is also an exploration of areas which are less familiar, and some cases where we feel less comfortable.

Our programme therefore combined both an examination of current pressing issues, as well as the new horizons presented by a rapidly changing European and global environment.

There is much to discuss! Our conference format tries to address a full range of current and future issues. We understand that some attendees will not have been able to attend all the parallel sessions that were of interest. We have therefore produced this short conference report which describes the main points from each parallel session and will hopefully provide some insights into the sessions attendees were unable to attend.

We would also like to use this occasion to share with you the visual notes taken during CEAC 2019 panel discussions and parallel sessions.

As always, we would welcome feedback on topics of interest for next year. In the meantime, we hope you will find our report a useful addition to the conference experience.

We look forward to seeing you at CEAC 2020!

John Chave, Director General, Cosmetics Europe

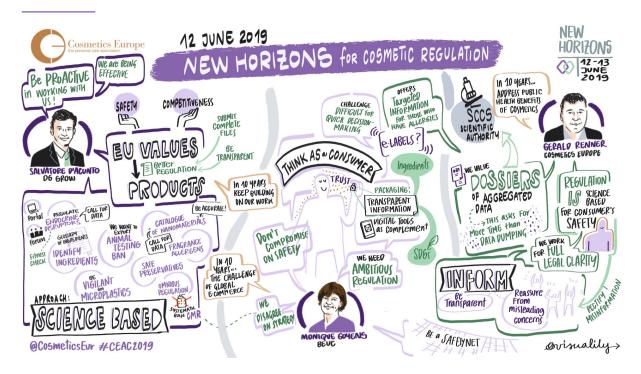
PANEL SESSION

New Horizons for the Cosmetics Regulation

Speakers:

Salvatore D'Acunto, Head of Unit, Health Technology & Cosmetics, DG GROW, European Commission Monique Goyens, Director-General, BEUC

Gerald Renner, Director Technical Regulatory Affairs, Cosmetics Europe



PARALLEL SESSIONS - AM

A. Microplastics restriction proposal

Speakers:

Meglena Mihova, Managing Partner, EPPA

Clare Liptrot, Product Safety & Regulatory Affairs Manager, Croda International

The session aimed at exploring the intricacies behind the European Chemicals Agency ongoing restriction proposal process for a REACH restriction on intentionally added microplastics and the possible impacts for the cosmetics and personal care industry.

The session started with an overview of the current proposal with a focus on the specific provisions for the cosmetics sector, including all proposed restrictions (including transition periods) and derogations.

The session continued with two presentations, during which the main concerns from the cosmetics sector (as downstream users) and the suppliers of cosmetics ingredients were introduced. During the Q&A session, several key points were discussed by the audience and the speakers, such as the point around labelling and reporting the use of derogated microplastics, the proposed scope of the restriction and the impact for both downstream users and suppliers.

Overall the session was very well attended and successful in informing the audience of the current activities and concerns of the industry regarding this Restriction Proposal.

B. Industry communicates - insights on the best communication strategies

Speakers:

Ronald Van Welie, Director, NCV

Frédérick Warzée, Head of Communications and Corporate Sectoral Sustainability, DETIC Irene van Luijken, Communications Director, CEFIC

Jana Zaric, Public Relations Director, EURACTIV



This parallel session aimed at presenting CEAC 2019 participants with the examples of the best practice in communicating the industry related matters externally to a broader audience.

Speakers representing trade associations shared their best tips and tricks, methods and strategic approaches that had already been put to use and validated in their daily work.

Ronald Van Welie (NCV) elaborated on the core aspects of development of an integrated trade association communication strategy. Among others, he highlighted the importance of a thorough analysis, defining mission and vision, focusing on positive storytelling, strong messages and strategic themes as well as building new and strengthening existing relationships.

Frédérick Warzée (DETIC) presented how the philosophy of the association has become the basis for the association's communication strategy encompassing crisis communication, pro-active communication and pre-active communication. He also underlined three main strategic pillars, i.e. credibility, assertiveness and cost efficiency and explained the benefits of the co-creation process.

Irene van Luijken (CEFIC) built on the importance of considering all external engagement as having potential reputational impact. She presented the "ChemistryCan" campaign, which aims at positioning the European chemical industry as sector playing an active role in creating a more sustainable economy in Europe. Various communication tactics and tools used in this campaign were presented and discussed.

Finally, Jana Zaric from EURACTIV introduced the perspective of a media organisation and advised on how to get media attention. She particularly stressed the importance of systematic and pro-active engagement with media representatives and providing relevant, exclusive and focused content.

C. How open is open? Transparency of safety assessment and safety assessment procedures

Speakers:

Genevieve Michaux, Partner, Mayer Brown Ellen Pfrommer, Head of Product Stewardship Personal Care, BASF

In view of the growing public demand for transparency of information in the risk assessment processes, as illustrated by the glyphosate debate and the recently adopted regulation on transparency in the food chain, the breakout session aimed at discussing to which extent such transparency requirement may be introduced for the cosmetics risk assessment processes as well, in connection with ingredient defence files submitted to the SCCS.

The panel explored how cosmetics data is currently being protected when submitted to the SCCS and what potential developments could occur in the future, given the current public and legal climate. Currently, only the SCCS Rules of Procedure provide for some language on transparency and confidentiality, and any transparency related requests will be dealt with via the horizontal legal framework. Based on recent case law, the frame regarding what can be treated as "confidential business information" is very tight, and legally challenging any transparency request on this basis may be difficult. Whilst the SCCS opinions are very detailed regarding the data submitted, the question on transparency cannot be raised without looking also at information regarding ingredients used in cosmetics but that are not listed in the annexes to the CPR.

D. China/India ready to align with international best practices?

Speakers:

April Guo, Cosmetics Regulatory Affairs Manager, Chemical Inspection and Regulatory Service (CIRS)

Janice Ma, Director APAC Regulatory Affairs, L'Oréal Malathi Narayanan, Secretary General, IBHA India

April Guo from CIRS presented trends for the market growth and product registrations, demonstrating that China remains a key market for European products and explained recent and upcoming regulatory changes to the cosmetics legislation. Participants discussed the impact of these in particular on importers of cosmetics into China.

The new basic legislation, CSAR, expected to be published in the course of 2019, has the potential to create a modern regulation, in line with international practice. It will be important that the implementing rules follow the principles outlined in CSAR. Important implementing rules to watch out for: Safety Assessment guidelines, labelling/claim substantiation, cosmetovigilance.

Requirements for importation of non-special cosmetics will be further aligned to domestic products. Moving towards a true notification approach and allowing safety assessments to replace the currently mandatory animal tests will boost trade opportunities for third countries as well as the development of the Chinese domestic industry. However, importers will have to have an authorities' statement that the product was manufactured under appropriate Quality Management System.

The lack of approval of new ingredients remains a major obstacle. A new process will likely differentiate between 'high' and 'low' risk ingredients, with the latter requiring a notification rather than premarket approval. An open question is the type of information that will be required notification and whether non-animal alternatives will be accepted.

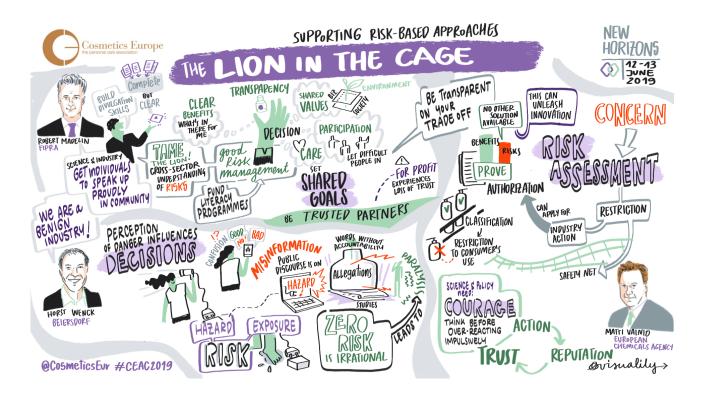
Malathi Narayanan presented the main changes that the Draft Cosmetics Rules, when implemented, will bring to our sector in India. One of the main achievements is that by regulating cosmetics separately from drugs, Indian authorities recognised that cosmetics should be treated as low risk and fast-moving goods. Some provisions of the new draft rules are, however, still of concern, notably the introduction of the concept of "new cosmetic ingredients" and the increase of the registration fees for the importers. The speaker stressed that she is confident that thanks to the advocacy efforts by IBHA, CE and PCPC, some of the current concerns will be solved in the final text to be released. The upcoming joint workshop to be organised in Delhi will also allow the industry to address remaining challenges in India such as simplification of the rules, promotion of horizontal standards and continue efforts to foster closer alignment between the EU and India.

PANEL SESSION

The Lion in the Cage – Supporting Risk Based Approaches

Speakers:

Robert Madelin, Chairman, Fipra International Horst Wenck, Corporate Vice President Front End Innovation, Beiersdorf Matti Vainio, Head of the Risk Management Implementation Unit, European Chemicals Agency



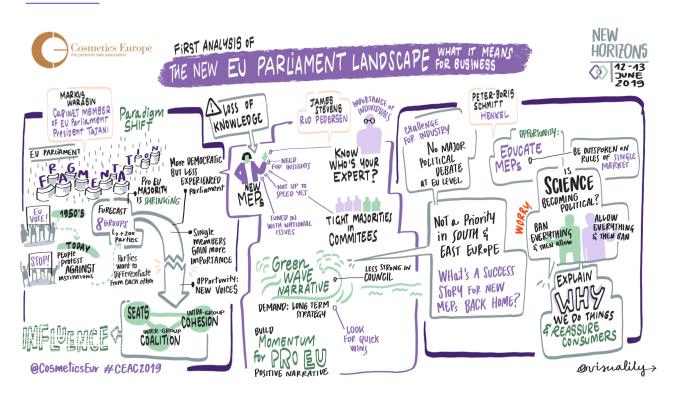
PARALLEL SESSIONS - PM

A. First analysis of the new European Parliament landscape - what it means for business

Speakers:

James Stevens, Partner, Rud Pedersen

Markus Warasin, Cabinet Member of the European Parliament President Tajani Peter-Boris Schmitt, Head of EU Office and Senior Manager, Political Environment and Products Affairs, Henkel



Following the May 2019 EU elections, the session provided initial analysis on the expected political dynamics in the new European Parliament, the EU's possible future direction and what this could mean for the European cosmetics industry and public affairs experts.

The elections attracted more interest from citizens, with an 8 point increase in the EU-wide participation rate. However, traditional centre-right and centre-left parties have lost influence over EU issues. Voters chose to a degree between pro- & anti-EU integration national parties. Further, not only the Greens political parties achieved good results in western EU Member States, but their ideas have been taken on by other EU political groups, which has consequences for EU priority orientations.

The result of the voting trends means: a more fragmented European Parliament, the support of more political groups needed to achieve majorities, and more struggles to ensure intra-group cohesion/coalitions. As politics is local, nationally-driven agendas and issues will continue to influence this new European Parliament.

The new EU institutional environment could take the following form for this term:

- Politically weaker Parliament (at least at the beginning);
- Stronger and more influential Council as Member States are taking back control over EU integration; and
- Less political, and more subordinated to the Council, European Commission.

For the European cosmetics industry, the next five years are expected to be both challenging and filled with new opportunities. The industry should take the opportunity to engage with newly elected MEPs as soon as possible (turn-over is estimated at 63% of new MEPs!), and with the reshuffled Commission in 2020, while consolidating its presence in the Member States. Policy trends from the past five years are expected to stay and the growing 'politicisation' of science could constitute a challenge.

B. New horizons for consumers

Speakers:

Stéphane Truchi, President, IFOP Anita Willemars, Journalist and blogger

New Horizons for Consumers explored a key challenge (and opportunity) for our industry – the growing proportion of our population who are older citizens. Two fascinating presentations were given. The first, by Stéphane Truchi from the French consumer research company IFOP, was entitled 'Silver is the New Sexy' and explored attitudes to ageing, well-being and beauty among older consumers across the globe. The second, from blogger, vlogger and journalist Anita Willemars, gave a direct perspective on how older consumers feel about our industry and its products.

Both presenters described older consumers in a way which is inconsistent with stereotypes. Older consumers are open to new experience, have significant disposable income, are highly focused on appearance and well-being, and frequently report feeling younger than they actually are. In fact, rigid distinctions between 'young' and 'old' in terms of attitudes and tastes are becoming increasingly outmoded. Both also noted that while we frequently read surveys and presentations on the needs of Millennials or Generation Y, attempts to understand how older generations think, feel and consume are less common. But older generations are a vast and growing market for cosmetics and personal care.

Is our industry doing enough? Both speakers thought the answer to this question is 'no'. The industry is to an extent using stereotypes in its approach to older consumers. There has not been enough effort to understand the needs of older citizens, despite their importance in the marketplace. Our industry needs to make more effort to tailor both products and importantly, marketing, to the new demographics. Silver really is becoming the new sexy, as displayed both in the remarkable attitudes survey presented by Stéphane, and the colourful and vibrant presentation from Anita. Industry take note.

C. How to address packaging in the Cosmetic Product Safety Report

Speakers:

Anne Fuchs, Associate Director, Kao Europe Research Laboratories Veronique Widemann, Head of Regulatory Affairs, Albéa Group

Veronique Wideman, Albea introduced the topic, explaining that cosmetic product safety assessments must consider the impact of the packaging on the safety of the formulation. Cosmetics Europe together with supplier associations developed an approach for the exchange of relevant information allowing the safety assessor to conclude if a packaging material/item has an impact on the safety of the cosmetic formulation. The approach is modelled on the example of food-contact material.

Anne Fuchs from Kao demonstrated how the data can be used in practice by the safety assessor. Migration from packaging into the formulation is usually trace issue and not a main driver for formulation. It can typically be addressed with worst-case assumptions and TTC considerations and does not require very detailed quantitative assessment. The information provided through the common approach provides a solid basis for such assessments.

The discussion highlighted that finished cosmetic packaging components are usually not tested for Specific Migration Limits and therefore not formally demonstrated as food contact compliant (because they are not used as such for food packaging). However, packaging raw materials used for both food and cosmetics packaging can have relevant migration information. Also, Overall Migration Information on the finished component can allow a TTC estimation. Existing food simulants can cover a wide range of cosmetic formulations, but certain product categories (e.g. extreme pH, high level silicone) may not have an analogous food simulant and there is an interest in developing cosmetic simulants. In principle, the approach should also work for recycled materials.

The approach is not yet widely implemented across the supply chain and more work needs to be done to 'roll it out' by the respective trade associations.

D. New Frontiers: Cosmetics in North America

Speakers:

Beta Montemayor, Director, Science, Regulation & Market Access, Cosmetics Alliance Canada

Francine Lamoriello, Executive Vice President - Global Strategies, Personal Care Products Council

During this session the latest regulatory developments in the US and Canada were presented.

On the US front, Francine Lamoriello explained that last year, 38 States were responsible for the issuance of 285 state bills related to cosmetics. This proliferation of initiatives makes the nation-wide approach very complex and the federal cosmetic reform going on could be an answer for better harmonization. She also presented the current "hot topics" such as environmental impact of sunscreen ingredients, ingredient disclosure, animal testing ban and the tentative final monograph for sunscreens.

On the Canadian front, Beta Montemayor offered a preview on the future "self-care framework" that will be introduced soon in Canada and that aims to address the innovation trend towards more active cosmetics.

These two presentations led the audience to discuss the opportunity that the new "self-care" approach in Canada could bring in terms of the recognition of cosmetics for the public health and the possibility to create a new mindset on risk-benefit. The recent inclusion of a cosmetic annex in the NAFTA agreement was also a reason to explore whether the US could mimic the Canadian approach in the future.

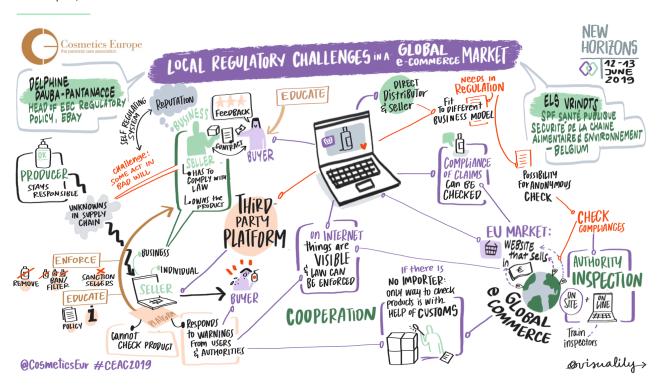
PARALLEL SESSIONS

A. Local regulatory challenges in a Global e-commerce market

Speakers:

Delphine Dauba-Pantanacce, Global Senior Legal Counsel, Head of EEC Regulatory Policy, Ebay

Els Vrindts , Inspector Officer and Coordinator, Belgian Competent Authority, SPF Santé Publique, Securité de la Chaine Alimentaire et Environnement



The session aimed at exploring how, today, authorities can ensure a level-playing field in terms of regulatory compliance between all economic actors selling cosmetics on-line and/or off-line.

Market surveillance with respect to products sold on-line remains a challenge, but the Belgian cosmetic competent authorities, in close cooperation with customs authorities, have put in place several tools to be able to enforce the cosmetics products regulation on-line. Priorities must however be set, and the focus of the authorities is on products that may represent serious health issues to the consumers. Cooperation with other European competent authorities remains an important aspect for the market surveillance on-line. Many products come into Europe through E-commerce marketplaces (such as eBay or Amazon) and cooperation with such platforms remain important, to ensure regulatory compliance and the sale of safe products on these platforms. Depending on the business model of the platforms, authorities may even consider them as part of the supply chain for cosmetics products, with related rights and obligations under the cosmetics regulation. eBay, in turn, dedicates many resources to ensure that the suppliers using their services are compliant with local regulatory frameworks, through internal policies and guidelines provided to their sellers.

B. Modulating the skin microbiome - Regulatory and safety aspects under the EU Cosmetics Regulation

Speakers:

Bernhard Paetzold, Co-founder & CSO of S-Biomedic Gerald Renner, Director Technical Regulatory Affairs, Cosmetics Europe

Bernhard Paetzold introduced the scientific background and concepts behind products that influence the skin microbiome. The number of scientific publications on the role of the human microflora in keeping the body 'in good condition' has been growing exponentially over the past years. Whilst the transfer of science to the market is already advanced for products influencing the gut microbiome, it is still early days for products influencing the skin microbiome. However, with pre- post-and probiotic cosmetics becoming a new and exciting trend, regulatory questions arise which were discussed in the breakout session.

In the discussion, participants assessed whether such products actually fall in the regulatory definition of cosmetics in the EU. Substances or mixtures of substances that are applied to the normal skin, including its microbiome in order to achieve a cosmetic function fulfill the three fundamental criteria of the EU Cosmetics Regulation (physico/chemical form, intended application site and primary function). The fact that the cosmetic function is achieved through a mechanism involving the skin microbiome does not influence this conclusion. It will, however, be important to clarify with regulators and control authorities that the existing guidance/recommendations on microbiological limits were designed for microbiological contamination and not for the deliberate use of microorganisms.

In principle, the normal safety paradigm for cosmetics applies also for these products. 'Normal' safety assessment methods apply as such to pre- and postbiotic ingredients. However, for ingredients made from life organisms (probiotics), specific additional aspects need to be considered, including:

- · Strain selection (pathogenic risk),
- Strain activity (biological/toxicological risk),
- Natural occurrence of the strain at the applications site vs. grafting → strain persistence,
- · Ability to remove the strain from the skin.

C. Latest developments in the SCCS world

Speakers:

Natacha Grenier, Policy Officer, Country Knowledge & Scientific, Committees, DG SANTE, European Commission

Vera Rogiers, Professor, VUB

George Manikas, Policy Officer, DG GROW, EuropeanCommission

At the SCCS parallel session, Natacha Grenier (SCCS Secretariat) gave an update of the SCCS current activities and provided some insight into the new and future mandates including the review of ingredients listed on the EC Endocrines priority list. On top, the SCCS is working on the

next revision of their notes of guidance with emphasis on how safety assessment can be done without animal testing.

George Manikas from DG GROW's Cosmetics Unit, continued with a workflow outlining the complete process from dossier submissions to entry into force of an ingredient specific regulation. He also provided recommendations for applicants to help make this process as efficient as possible.

Prof. Vera Rogiers (VUB and Co-Chair of SCCS) informed the audience about the ongoing discussion at the SCCS Working group on the methodology in particular on the 'New Generation Risk (Safety) Assessment' which should, in her view, be exposure and hypothesis driven. The SEURAT workflow (which is adopted by the OECD and ICCR) is considered a good assessment framework to show how alternative approaches can be applied .SCCS will take into consideration a number of new approaches including: TTC (thresholds of toxicological concern), in silico tools (e.g. QSAR's), Read Across, PBPK modelling and Internal TTC.

The discussion that followed focused to a large extent on the Endocrine priority list and the challenges that this is bringing both to industry, SCCS and regulators.

D. Is there one global solution for the unique product identifier?

Speakers:

Christoph Staub, VP Global Business Development & Strategies, Laetus

Anne Laissus-Leclerc, Sub-contracting, Technical and Regulatory Affairs Director, LVMH

This session aimed at providing an overview of the journey that started from a wish of the industry to provide some information about the product off-pack, to the recent coding requirements in preparation in several regions of the world to enhance product traceability and fight against counterfeiting.

Anne Laissus-Leclerc discussed the Cosmetics Europe pilot project to digitalize the ingredients list and demonstrate on a larger scale its technical feasibility. However, the presentation showed that the EU is not driving the agenda anymore, and that regulatory initiatives are starting around the world, which represents a big challenge for our industry, especially in the case of Russia who is setting up a full serialization and track and trace system for perfumes.

Christoph Staub, building on his vast expertise in the pharma sector, presented what the track and trace system means in practice, its challenges but also benefits for the companies.

The presentation led the audience to wonder if, in the view of the different initiatives starting around the globe, there was still a solution for a global unique product identifier and what should be the principles this UPI should follow to ensure flexibility and relevance at international level. More importantly, the audience agreed on the significance of defining a system fit for purpose for our industry.

PANEL SESSIONS

'Beauty in the eyes of 10 billion beholders on one planet? Creating an industry in which future fitness is more than skin deep'

Speakers:

Ed Gillespie, Sustainability Futurist and Board member, Greenpeace UK



Reflections on New Horizons

Speakers:

Birgit Huber, Deputy Director General, IKW

Hervé Toutain, Senior Vice President - Product Stewardship & Public Affairs, L'Oréal

